

SUMMARY-- STARKEY TM - SERIES SUBSTANTIAL EQUIVALENCE

The Starkey TM air conduction high frequency tinnitus maskers are designed to be behind-the-ear maskers. This form of masker is intended to be received by a Hearing Health Professional in a completed form, not being intended for final assembly.

The Starkey TMs are substantially equivalent to the masking portion of the Starkey CE-8 TML/TMC (K940667). The Starkey TMs are BTE Tinnitus Maskers with a white noise generating circuit which can be tuned to match the frequency and intensity of ringing in the patient's ears (head). The patient has a volume control for this circuit. Variable high and low frequency cut potentiometers can be set by a Dispenser to tune to more specific frequencies. All other aspects of these tinnitus maskers are similar to the masking portion of the Starkey CE-8 TML/TMC.

Starkey TM Series

- BTE
- Adjustable Masker Level Control
- Variable Low Frequency Cut (L)
- Variable High Frequency Cut (H)
- Dispenser can tailor to meet individual needs using (L) and (H).
- Made with standard hearing aid parts
- Uses standard hearing aid 675 battery

Starkey CE-8 TML/TMC

- Custom ITE
- Adjustable Volume Control
- Adjustable Masker Frequency
- Adjustable Masker Level Control
- Color Coded for Left and Right
- Hearing aid response tailored to individual needs
- Made with standard hearing aid parts
- Uses standard hearing aid 13 battery

SAFETY AND EFFECTIVENESS SUMMARY - STARKEY BTE TM SERIES

NAME OF DEVICE: Starkey TM Series air conduction high frequency tinnitus maskers.

TYPE OF DEVICE: Standard BTE air conduction maskers -- Substantially equivalent to the Starkey masking portion of the CE-8 TML/TMC hearing aid, (K940667)

INTENDED USE: To generate a pleasant white noise stimulus to aid in masking the user's tinnitus (or ringing in the ears)

FEATURES: Adjustable masker volume controls, control for adjusting the high and low masker frequencies.

ASSEMBLY: Assembled from standard components that are widely used in hearing aid devices throughout the industry.

TECHNICAL CHARACTERISTICS: Technical specifications comply with ANSI S3.22-1987

FIT: Masker frequency response varying based on the needs of the patient. Tolerances are maintained to a ± 4 dB range for SSPL.

CONTROLS: Volume controls, similar to those used on other hearing aid devices. Pots or switches are similar to those used in other hearing aid devices.

POWER: Standard 1.4 V type 675 hearing aid battery.

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